This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

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The assigned 510(k) number is: K011500

DEC 0 3 2001

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
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Date Prepared: July 18, 2001

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Device Name and Classification

Proprietary Name: Mentor Contour Profile Tissue Expander
Common Name: Tissue Expander
Classification Name: Skin Expander, Inflatable
Product Code: 79LCJ

Manufacturer

Mentor Texas
3041 Skyway Circle North
Irving, TX 75038

Device Description

The Contour Profile Tissue Expander is used for breast reconstruction following mastectomy. In order to provide a Tissue Expander with elasticity and integrity, the shell is made with successive cross-linked layers of silicone elastomer. Superior and anterior reinforcement allows for directional expansion in the lower pole of the device. The device has an integral, silicone elastomer, magnetically detectable, injection site. The textured Siltex shell provides a disruptive surface for collagen interface. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Identification of the injection port site can be accomplished by use of either the magnetic detection device provided with the Contour Profile Tissue Expander, by palpation of the

raised outer ring of the injection port, or use of any other manufacturer's tissue expander port detection devices.

The hand held magnetic port detection device consists of a magnet suspended from a spherical plastic mount. The mount is such that the magnet can incline freely within a 70° cone and designed to swivel, due to magnetic attraction, toward the center of the injection port of the Tissue Expander. The detector is moved around the site of implantation (over the surface of the patient's skin) until the magnet points directly at the hole in the base of the unit (the target) at which time the injection site has been located. Please refer to Attachment B, "Device Drawing Specifications", for a drawing of the port detection device.

To use the magnetic detection device (or any other manufacturer's device), follow the instructions provided with the specific device. Injections must be made using sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection and into the area enclosed within the palpation ring. Although the Contour Profile Tissue Expander has a self-sealing patch surrounding the injection port to prevent and/or protect against leakage due to inadvertent needle punctures, injections made on or outside the palpation ring, can result in leakage.

Substantial Equivalence Claim

The Mentor Contour Profile Tissue Expander is substantially equivalent in material, function, performance and design to the tissue expander products manufactured and marketed by Mentor Corporation, 510(k) No: K884250 and McGhan 510(k) No: K862203.

Indications for Use

The Contour Profile Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The device is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Summary of Testing

All mechanical testing specifications comply with established ASTM and other internal Mentor standards for Shell/Patch Joint Strength, Critical and Non-Critical Joint Strength, Leak Testing, Tensile Strength, Overexpansion, Break Force and Tear Strength.

All biocompatibility testing complies with established ASTM, ANSI/AAMI and internal Mentor standards for Intracutaneous, Sensitization, Cytotoxicity, Intradermal Irritation, Implantation, Systemic Toxicity, Bioburden, and LAL Endotoxin testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Ms. Donna Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

Re: K011500
Trade Name: Mentor Contour Profile Tissue Expander
Regulatory Class: unclassified
Product Code: LCJ
Dated: November 5, 2001
Received: November 6, 2001

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Walker, MD

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011500

Device Name: Mentor Contour Profile Tissue Expander

Indications for Use:

The Contour Profile Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011500

Prescription Use X or Over the Counter Use _____
(Per CFR 801.109)

(Optimal Format 1-2-96)